

ONLINE FIRST

Patient Outreach to Promote Colorectal Cancer Screening Among Patients With an Expired Order for Colonoscopy

A Randomized Controlled Trial

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Background: Targeted interventions to promote colorectal cancer screening among specific populations could increase screening rates. Patients with an expired order for screening colonoscopy might be persuaded to follow through with screening by such an intervention.

Methods: We conducted a randomized controlled trial of a combined reminder/outreach intervention among patients in a large general internal medicine practice. Participants included 628 patients aged 50 to 79 years with an expired order for screening colonoscopy. Patients were stratified based on receipt of any previous colorectal cancer screening and randomly assigned either to (1) an intervention group that received a mailing containing a reminder letter from their primary care physician, a brochure and digital video disc about colorectal cancer and colorectal cancer screening, and a follow-up telephone call or (2) a usual care control group. The primary outcome was receipt of fecal occult blood testing, sigmoidoscopy, or colonoscopy within 3 months of randomiza-

tion. Screening outcomes were observed for an additional 3 months (6 months from randomization).

Results: Screening rates at 3 months were 9.9% (31 of 314 patients) in the intervention group and 3.2% (10 of 314 patients) in the control group (rate ratio, 3.1; 95% confidence interval, 1.5-6.2; $P = .001$). At 6 months, rates were 18.2% (57 of 314 patients) and 12.1% (38 of 314 patients), respectively (rate ratio, 1.5; 95% confidence interval, 1.03-2.2; $P = .03$).

Conclusion: Patient outreach to individuals with an expired order for colonoscopy may be an effective tool to modestly increase short-term completion of colorectal cancer screening.

Trial Registration: clinicaltrials.gov Identifier: NCT00793455

Arch Intern Med. 2011;171(7):642-646.

Published online December 13, 2010.

doi:10.1001/archinternmed.2010.468

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COLORECTAL CANCER IS THE second leading cause of cancer death in the United States.¹ Screening detects early-stage cancer when it is more curable and reduces colorectal cancer incidence and mortality,²⁻⁴ and periodic screening for individuals at average risk beginning at age 50 years is recommended by the US Preventive Services Task Force (USPSTF) and a number of national organizations.^{3,5,6} Unfortunately, colorectal cancer screening remains widely underutilized: 40% to 50% of the 90 million Americans who may stand to benefit have not been screened.⁷

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Numerous interventions to promote screening have been directed at the level of the patient, the health care provider, and the

system. The results are varied. A recent Agency for Healthcare Research and Quality systematic review assessed the effectiveness of interventions to improve colorectal cancer screening rates.^{8,9} The review found that patient reminders produce a small to moderate increase in screening. "Small media," defined by the reviewers as mailed

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at end of article*

or provided print or video educational materials, without decision aids generally have not been effective. Health care provider-directed approaches (eg, physician reminders, performance measurement, and feedback) have been effective at increasing the use of some preventive services¹⁰⁻¹² but have not been clearly shown to increase colorectal cancer screening.⁸ System-level

interventions, such as using nonclinicians to support screening and assisting patients in keeping appointments, have been effective but are resource intensive.^{8,9}

Practices seeking to improve the delivery of colorectal cancer screening must do so with finite resources. Most prior studies have not tested targeted strategies to promote screening among specific subpopulations. Determining whether specific approaches are effective for identified patient subgroups could help practices increase their efficiency. One such target group is made up of individuals who have received a referral for colonoscopy but have failed to follow through on the screening itself. These patients might benefit from materials targeted specifically to their situation.¹³ Some of these patients who receive an order for colonoscopy but do not follow through may be more willing to undergo screening with a less invasive test like fecal occult blood testing (FOBT), but they may not have been advised by their physician about other screening options.

Therefore, we designed an intervention to focus on patients who have received and accepted a referral for colonoscopy, yet have exhibited some barriers to screening as demonstrated by a lack of screening completion. We conducted a randomized controlled trial to assess the effects of a multicomponent intervention (patient reminder, print and multimedia materials, follow-up telephone call for process evaluation) on colorectal screening completion among this target population.

METHODS

STUDY SETTING

This trial was conducted between October 2008 and May 2009 at a large urban academic adult primary care internal medicine practice in Chicago, Illinois. This practice uses a commercial electronic health record (EHR) (EpicCare, version Spring 2007; Epic Systems Corporation, Verona, Wisconsin). Clinicians already receive point-of-care reminders and quarterly performance feedback for a variety of preventive health and chronic disease topics including colorectal cancer screening.¹² Internal performance reports indicated that when the study began, 59% of the patients at the practice who were eligible for colorectal cancer screening were up to date. In this practice, colonoscopy orders expire after 3 months; patients may contact the practice to request a new order. Wait times for colonoscopy at this site are relatively short (<1 month). All physicians provided written consent to allow the study staff to randomize patients with expired screening colonoscopy orders to an intervention group that would receive an immediate multicomponent outreach or a control group that would receive an outreach letter after 6 months. Physicians consented to allow the study staff to use their digital signatures in patient mailings.

PATIENT ELIGIBILITY AND RANDOMIZATION

Using data contained in the EHR, we identified patients aged 50 to 79 years who had received an order for a colonoscopy but had not completed it within 3 months of the order. We lowered the upper age limit during the study to 75 years to coincide with the revised USPSTF screening recommendations.³ We excluded patients who had a colonoscopy ordered to evaluate symptoms (eg, not a screening order); had a previous diagnosis of colorectal cancer or colon polyps; had received multiple colorectal cancer screening orders within 3 months; or if

on medical chart review the patient had psychosocial or medical issues (eg, recent loss of spouse, recent diagnosis of breast cancer) for which colonoscopy was deemed inappropriate at the time. When the intervention began in October 2008, all patients with an order that was placed at least 3 months earlier, but not prior to February 2008, were eligible. Patients who subsequently became eligible were added to the eligible population prospectively until the target study size was reached. Groups of eligible patients (based on the week they became eligible) were stratified based on prior colorectal cancer screening (repeat vs never) and then randomly assigned in equal numbers to either the control or intervention arms using a random number generator. The group assignments were not revealed until after randomization was completed. If we were unable to ascertain whether the patient had been screened previously for colorectal cancer, the patient was considered to be never screened.

INTERVENTIONS

Patients in the intervention group were sent a mailing consisting of a personalized reminder letter from the physician, an educational brochure, and a digital video disc (DVD) about colorectal cancer and colorectal cancer screening. In addition, patients were called 2 weeks following the mailing to complete a brief process evaluation. The DVD ("Get Screened for Colorectal Cancer Patient Education Program") was designed based on the Extended Parallel Process Model of health behavior change.¹⁴⁻¹⁸ It outlined common myths and questions regarding colorectal cancer and screening. The DVD and the brochure also provided the patient with information on FOBT as well as colonoscopy. The DVD used in this study was created within Northwestern University's Division of General Internal Medicine.¹⁴⁻¹⁶ Previous research demonstrated the effectiveness of the DVD in increasing patient knowledge about colorectal cancer and colorectal cancer screening.^{14,15} We anticipated that not all patients would view the DVD. Ergo, clinical and research faculty developed a 1-page, double-sided educational brochure that included content similar to the DVD. The letter was included because we believed that a personalized statement from a patient's own physician that included his or her digital signature and the date the colonoscopy was ordered might be more salient to some patients than an impersonal brochure alone. The letter reminded patients that the physician had ordered a screening colonoscopy and reiterated the importance of screening even if patients had no symptoms or family history. Both the letter and the brochure included the clinic telephone number and asked patients to call for an updated order. The median elapsed time between the colonoscopy order and the mailed intervention was 3.4 months (interquartile range, 3.2-5.2 months).

Control group patients received usual care. After the date of the 6-month follow-up had elapsed, we mailed control group participants a tailored letter signed by their physician that reminded them of their uncompleted colonoscopy and restated the importance of colorectal cancer screening.

STUDY OUTCOMES

We anticipated that if this 1-time intervention was effective, the impact would be present close to the time that patients received the intervention. Therefore, as the waiting times for colonoscopy are short at this center, the primary study outcome was the completion of colorectal cancer screening using FOBT, flexible sigmoidoscopy, or colonoscopy during the 3 months after randomization. Double-contrast barium enema and computed tomography colonography were not included because these tests were rarely used within this practice. As a second-

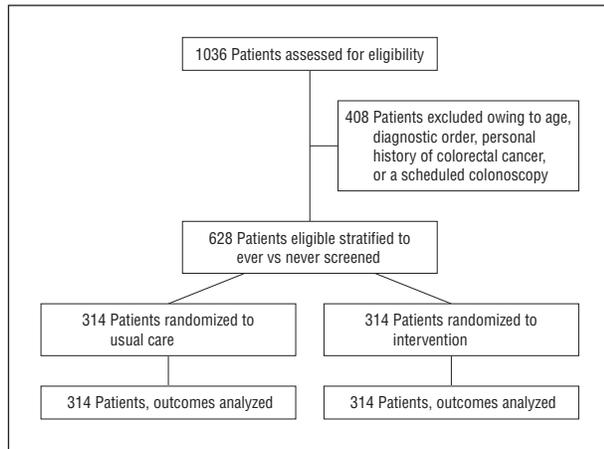


Figure 1. Study flow diagram.

Table. Baseline Characteristics of Patients by Randomization

Characteristic	Control (n=314)	Intervention (n=314)	P Value
Age, mean (SD), y	58.03 (6.6)	57.90 (7.1)	.82
Female, No. (%)	192 (61.1)	197 (62.7)	.68
Race/ethnicity, No. (%)			
White	132 (42.0)	144 (45.8)	.55
Black	77 (24.5)	79 (25.1)	
Hispanic	14 (4.5)	9 (2.87)	
Other/unknown	91 (28.9)	82 (26.1)	
No. of visits in past 2 years, No. (%)			
1-2	79 (25.1)	69 (21.9)	.78
3	79 (25.1)	80 (25.5)	
4	48 (15.3)	54 (17.2)	
≥5	108 (34.4)	111 (35.3)	
CRC screening history, No. (%)			
Ever	24 (7.6)	22 (7.0)	.76
Never	290 (92.4)	292 (93.0)	
Previous orders, mean (SD), No.	1.54 (1.6)	1.48 (1.5)	.67
Insurance status, No. (%)			
Private	236 (75.1)	245 (78.0)	.78
Medicare	63 (20.0)	56 (17.8)	
Medicaid	10 (3.2)	10 (3.2)	
Uninsured	5 (1.6)	3 (0.9)	

Abbreviation: CRC, colorectal cancer.

ary outcome, we determined if colorectal cancer screening was completed within 6 months following randomization. Outcomes were measured using automated review of electronic data supplemented by manual medical chart review by a reviewer unaware of the study group assignment at the time of review.

DATA ANALYSIS

We compared baseline characteristics among patients in the intervention and control groups using independent samples *t* tests for normal continuous variables, Wilcoxon rank sum test for nonnormal continuous variables, and the χ^2 test for dichotomous variables. For analyses of the study outcomes, we tested the proportional hazards assumption over the full 6-month study period. Because this assumption was not valid, we compared the outcomes in the intervention and control groups using rate ratios and the χ^2 test at 3 and 6 months; a

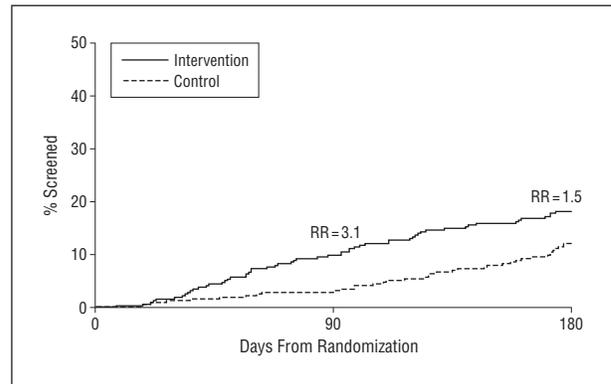


Figure 2. Time to screening completion. RR indicates relative risk.

2-sided test with a *P* value of $<.05$ was used to determine significance. The study was powered to detect a 10-percentage point difference in screening completion between intervention and control groups if the control rate of completion was 20% or less with 80% power.

We also conducted a brief process evaluation among patients in the intervention group. Two weeks after the mailings were sent, we attempted to contact all intervention group patients via telephone. Three call attempts were made to reach each participant. We asked patients if they received a package from their physician containing a letter, a brochure, and a DVD about colorectal cancer screening; if they read the letter and enclosed brochure; and if they watched the DVD. If during the telephone call participants reported questions related to colorectal cancer or colorectal cancer screening, they were given the clinic's telephone number and encouraged to call with those questions.

The institutional review board of Northwestern University approved the study protocol, which included a waiver of informed consent. Physicians gave their approval to contact patients with expired and incomplete orders for colonoscopy.

RESULTS

Of the 1036 patients assessed for eligibility, 408 were excluded because of age, personal history of colorectal cancer, documentation of a scheduled (not yet completed) colonoscopy, or evidence that the colonoscopy order was for a diagnostic colonoscopy and not a screening colonoscopy (Figure 1). A total of 628 patients were randomized to the intervention ($n=314$) and control ($n=314$) groups. The mean (SD) age of participants was 58.0 (6.9) years; 92.7% had no prior colorectal cancer screening captured in the EHR. There were no significant differences between control and intervention groups on measured demographic variables (Table).

After 3 months, 31 of the 314 patients (9.9%) in the intervention group and 10 of the 314 patients (3.2%) in the control group had completed colorectal cancer screening, an absolute difference of 6.7% (rate ratio, 3.1; 95% confidence interval [CI], 1.5-6.2; $P=.001$). Figure 2 displays the time to completion of colorectal cancer screening for the control and intervention groups. Of those patients who completed screening, only 1 patient in the control group and none in the intervention group completed FOBT. At 6 months, 18.2% (57 of 314) of the intervention group and 12.1% (38 of 314) of the control

group had been screened, an absolute difference of 6.1% (rate ratio, 1.5; 95% CI, 1.03-2.2; $P=.03$).

We reached 109 of the 314 intervention group participants (34.7%) by telephone to complete a brief process evaluation. Of those contacted, 95% reported receipt of the mailed intervention materials. Of those who acknowledged having received the mailing, 98% reported that they read the letter and the enclosed brochure and 30% reported watching the DVD. Participants provided open-ended responses to reasons for not watching the DVD. Primary reasons participants reported included the following: they were busy or had no time (32.4%); they perceived they already had sufficient information about screening (20.7%); they were not interested in screening (12.9%); or they did not have a DVD player or were unable to operate a DVD player (10.4%).

COMMENT

Among patients with expired orders for screening colonoscopy, we found a modest positive effect of a multi-component patient outreach intervention on colorectal cancer screening completion. The impact of the intervention appears to have occurred within the first 3 months; we did not observe any additional divergence in the screening rates during months 4 through 6. To our knowledge, this is the first intervention specifically targeted toward patients who have received an order for screening colonoscopy but did not complete it. The magnitude of our results is consistent with the effects seen in prior studies of mailed patient interventions directed at more general populations of patients eligible for colorectal cancer screening.^{8,19-22}

Patients who have seen their physician and received an order for a colonoscopy but did not complete the test are an important subgroup to target for quality improvement. Over the past 4 years, our practice has implemented multiple system changes to promote colorectal cancer screening and other preventive services.^{11,12} As of August 1, 2010, 70% of patients in the practice were up to date on their colorectal cancer screening. Of the 30% not up to date on screening, almost half (43%) had an order placed for a colonoscopy that was not completed. To achieve the highest level of care possible for colorectal cancer screening, effective interventions that target this patient subgroup are needed.

We learned several practical lessons relevant to the promotion of colorectal cancer screening using patient-directed interventions in this noncompleter population. First, in an intervention that combined a mailed personalized letter, an informational brochure, and a DVD, less than one-third of patients contacted said they watched the DVD. Patients commonly reported that they did not have time to watch it or believed that it would not provide any new useful information. The fact that our DVD, considered to be a small medium, appeared to have little to no effect is consistent with other studies using small media interventions.^{8,21,23-25} This result suggests that it might not be worthwhile to include educational videos as part of mailed multicomponent patient outreach interventions. Re-

moval of the DVD component may also reduce the cost of such interventions, making their use more generalizable. Second, we thought that some colonoscopy noncompleters would have favorable views toward screening but be uneasy with the specifics of the colonoscopy procedure; thus, providing information about the FOBT could increase screening. The observation that none of the intervention group patients obtained a FOBT does not support this view. Patients who were motivated by the intervention to be screened may have been committed already to receiving colonoscopy but were unable to complete the screening previously or were simply procrastinating. Those patients who did not obtain any screening test after receiving the intervention may have had misgivings regarding colorectal cancer screening in general, lacked the motivation to pursue any screening test, or been uncomfortable with both the colonoscopy and FOBT procedures.

This study has several limitations. It does not identify the timing of the intervention that would have the most impact. Mailings occurred 3 months or more after the order was placed. Contacting patients and giving them a nudge closer to the time when the order was placed and the discussion with their physician occurred (eg, within 1 week) may have been more effective. In addition, we are unable to comment specifically on the utility of each component of the intervention and do not know which parts are most essential. The follow-up telephone calls we made to evaluate the intervention process essentially became part of the intervention, and we do not know if telephone calls are necessary to achieve the results we observed. Our study may not have been optimally designed to encourage patients to watch the DVD. Because our study included a mailed brochure, patients may not have thought they would gain additional benefit from viewing the DVD. Our study design does not tell us the nature and length of the discussions that occurred prior to physician placement of the order for the colonoscopy. Some physicians' discussions with patients about the need for colorectal cancer screening, the screening options available, and the risk and benefits of these options may have been brief and incomplete. If patients are still at the point of precontemplation or contemplation when the order is placed, it would be unlikely that the patient would complete the colonoscopy.^{24,26,27} Finally, we did not examine or address patients' reasons or greatest barriers to colonoscopy completion.

In conclusion, a combined print and multimedia patient outreach intervention increased short-term completion of colorectal cancer screening among the subgroup of individuals with an expired order for colonoscopy. Because the screening rate remained low, additional research is needed to determine how to best promote screening in this patient group. At present, health systems could reasonably choose to begin screening promotion with low-cost interventions like simple mailings followed by more expensive, but potentially more effective interventions such as one-on-one patient navigation or interventions aimed at eliminating structural barriers for patients who remain unscreened.^{21,28-31}

Accepted for Publication: October 19, 2010.

Published Online: December 13, 2010. doi:10.1001/archinternmed.2010.468

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Author Contributions: Dr Cameron had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Cameron, Persell, Brown, and Baker. *Acquisition of data:* Brown, Thompson, and Baker. *Analysis and interpretation of data:* Cameron, Persell, Thompson, and Baker. *Drafting of the manuscript:* Cameron and Brown. *Critical revision of the manuscript for important intellectual content:* Cameron, Persell, Thompson, and Baker. *Statistical analysis:* Cameron, Persell, and Thompson. *Obtained funding:* Baker. *Administrative, technical, and material support:* Brown and Baker. *Study supervision:* Cameron, Persell, and Baker.

Financial Disclosure: None reported.

Funding/Support: This study was supported by grant 1R18HS17163-01 from the Agency for Healthcare Research and Quality. Dr Persell was supported by career development award 1K08HS015647-01 from the Agency for Healthcare Research and Quality.

Role of the Sponsors: The funding organization did not have any role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; nor in preparation, review, or approval of the manuscript.

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